201-16269

RECEIVED
OPPT CBIC

06 JUN -6 AM 9: 16

June 5, 2006

Mr. Stephen Johnson, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 110 1 -A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

Subject: Public Comments on Chemtura Corporation's HPV Challenge Program Test Plan for Barium Stearate (CAS No. 6865-35-6).

The following comments on Chemtura Corporation's test plan for barium stearate are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Barium stearate is a solid material used as a lubricant/processing aid in PVC compounding. Chemtura cites dissociation studies demonstrating that barium stearate readily and completely dissociates at the pH of the mammalian stomach.

We commend Chemtura Corporation for applying this observation and proposing to supplement existing toxicity data for barium stearate with data for its dissociation products. This approach is consistent with the EPA's stated goals of maximizing the use of existing data in order to limit additional animal testing. A similar approach was endorsed by the EPA and all stakeholders in 2004 for E. I. du Pont de Nemours & Company's test plan for triisopropylborate, a compound which breaks down to isopropanol and boric acid in water. Chemtura cites acute toxicity studies for barium and stearic acid in fish, repeated dose studies for barium chloride and stearic acid in rats, and reproductive/developmental studies for barium chloride in rats. Although no reproductive/developmental studies with stearic acid are cited, stearic acid is the most common of the long-chain fatty acids. The catabolism of fatty acids is a well- documented metabolic process in animals and humans. Stearic acid falls within the molecular range of fatty acids normally metabolized by animals and humans, and has no structural characteristic that would indicate that it requires toxicity testing. Stearic acid is labeled a "Generally Recognized as Safe (GRAS)" food additive by the FDA. As such, the EPA recommends that participants consider whether the information supporting the FDA's conclusions makes it unnecessary to proceed with further testing of animals. Finally, stearic acid is being sponsored in the HPV Program by the Soap and Detergent Association. Genetic toxicity studies for barium chloride are also cited.

Additionally, Chemtura Corporation cites acute toxicity studies of barium stearate in rats (LD_{50} equals 2506 mg/kg to 3390 mg/kg) and mice (LD_{50} equals 1832 mg/kg) which show it to have low toxicity. With regard to aquatic toxicity, Chemtura notes barium stearate's low water solubility (3.5 mg/L), and proposes a chronic test in daphnia. Along with the acute toxicity data previously mentioned for the dissociation products, this approach adequately addresses the SIDS endpoints for ecotoxicity and health effects without additional animal testing for this chemical.

Thank you for your attention to these comments. I may be reached at 610-586-3975, or via e-mail at josephm@peta.org.

Sincerely,

Joseph Manuppello
Research Associate
Research & Investigations